Remarks/Arguments

The Examiner has rejected Claims 1-4 and 6-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In order to overcome this rejection, Applicants' attorney hereby states that the deposit has been made as an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

Applicants respectfully request reconsideration of the above rejection in light of the statement by Applicants' attorney.

The Examiner has maintained the rejection of Claims 1-4 and 6-10 under the written description requirement of 35 U.S.C. 112.

The Examiner maintains that the written description of the claimed enzymes requires more than a mere statement that they are part of the invention and reference to a potential method for isolating them. Supporting the Examiner's rejection is the contention that the specification has no evidence on the record that any enzyme was isolated. Rather, the Examiner argues that the specification describes only a microorganism or cells of a microorganism have been employed as a biocatalyst. Applicants respectfully traverse the Examiner's rejection.

Contrary to the Examiner's contention, the written description provided in the specification is completely consistent with the state-of-the-art for isolation and identification of enzymes from microorganisms. The Examiner states that a mere recitation of the means of isolation for a given enzymes which identifies a single microorganism from an assay of more that 96 strains shows no proof that the described enzyme was isolated. In fact, this is a very clear and well-recognized means for isolating a specific enzyme. Enzymes are proteins that catalyze innumerable reactions within the cells of millions of biological organisms. Many of these enzymes are identified and claimed based on a description of chemical elements that comprise them. However, such a description is in fact, inadequate, because it fails to describe the conditions under which the enzyme is operating. These conditions affect such critical requirements for enzymatic activity as folding of the protein. Contrary to such

an inadequate description, Applicant has identified the specific organisms and the particular reaction conditions under which the enzymes of the invention function in the claimed process. Any practitioner skilled in the art can quickly and easily isolate the enzyme of the claimed process based on the written description.

The Court of Appeals for the Federal Circuit has affirmed their position as to an inventor's possession of the invention in Moba, B.V., Staalkat, B.V., and FPS Food Processing Systems, Inc. v. Diamond Automation, Inc., 325 F.3d 1306, 66 U.S.P.Q. 2d 1429 (CAFC 2003). In that case, the CAFC stated that "The test for compliance with §112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention as the time of the original filing." Id. at 1320. Citing its own decision in Amgen, Inc. v. Hoechst Marion Rousel, Inc. 314 F.3d 1313, 65 U.S.P.Q. 2d 1385 (CAFC 2003), the court stated:

> "More recently, in Enzo Biochem, we clarified that Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure."

Amgen, 314 F.3d at 1332.

Accordingly, Applicants respectfully request that the Examiner reconsider the above rejection in light of the recent case law. Applicants assert that recitation of the means of isolation of the enzyme of the claimed invention is, in the knowledge of the art, sufficiently correlated to a particular, known structure and, therefore, that the written description is sufficient.

The Examiner rejected Claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the Examiner's rejections for the reasons stated above with respect to the rejections under the enablement requirement of 35 U.S.C. 112, first paragraph.

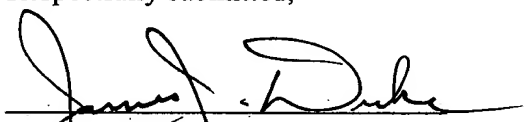
The Examiner rejected Claims 1-4 and 6-10 under 35 U.S.C. 102(b) as anticipated by WO 92/18477 or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 92/18477. As is described in the present application at page 3, line 21 to page 4, line 3, this reference discloses the use of an enzyme derived from Rhodococcus equi to transform racemic ß-lactams, giving one enantiomer as untransformed lactam, and the other as hydrolysis product (amino acid). The particular enzyme employed is, however, highly inefficient (as is explained at page 4, lines 1 to 3 of the present application).

Applicant has established and elucidated a test, which is able to ascertain in a simple and unambiguous way those enzymes (or more specifically, the microorganisms which produced them) which are suitable for use on an economic scale. The test is that set out at page 4, lines 8 to 20 of the application, namely that the material is capable of the enantioselective hydrolysis of racemic lactams of the formulae 2 and 3.

The Examiner has rejected this argument as arguing an alleged limitation not present in the claims - namely, a test for determining which enzymes are suitable for use on an economic scale. Applicants assert that the test merely provides the basis for a showing of novelty and unobviousness of the claimed enzymes. Contrary to the Examiner's assertion, there is no teaching or suggestion that the enzyme derived from Rhodococcus equi to transform racemic ß-lactams would yield resolutions within a commercially useful period of time, i.e., 48 hours. While all of the resolutions in the claimed process were carried out in under 48 hours with an enantiomeric excess of greater than 90%, the WO 92/18477 reference shows a resolution time of at least 142 hours, or nearly three times as long. See page 3, lines 30-31 of the WO 92/18477 reference. Accordingly, the use of the claimed lactamase enzyme for enantioselective hydrolysis is neither anticipated nor obvious in light of the WO 92/18477 reference.

Given these remarks and arguments, Applicant respectfully requests that the allowance of Claims 1-4 and 6-10 be reconsidered.

Respectfully submitted,



James J. Drake
Registration No. 34,584
Phone: 989-636-8449

P. O. Box 1967
Midland, MI 48641-1967

JJD/ajd